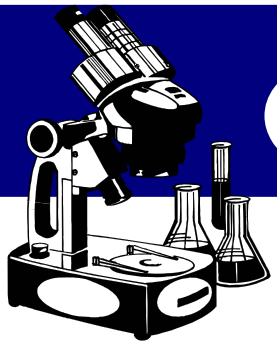


CLIA BITS

North Dakota Department of Health
Division of Health Facilities
Summer 2003

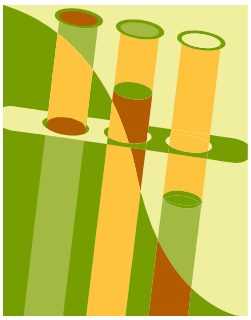
Non-Regulated Analytes

What steps should a laboratory take when it receives an unacceptable proficiency testing (PT) result on non-regulated analytes?

Non-regulated analytes are analytes not listed in Subpart I - Proficiency Testing Programs for Nonwaived Testing. CLIA does not require PT for non-regulated analytes but does require that laboratories verify the accuracy of these test results at least twice a year.

If a laboratory decides to enroll in proficiency testing for non-regulated analytes, the laboratory needs to take action for ANY proficiency test result that they do not obtain the correct answer for, or do not receive an accurate score from the PT company. We define unacceptable as the failure to obtain the expected result. For example, if a laboratory fails one out of two troponin results, they have one unacceptable result.

A laboratory must have a quality system in place to monitor all non-regulated analytes. If the laboratory is utilizing PT, a system needs to be in place to identify any proficiency testing problems. If the laboratory is not utilizing proficiency testing, there still must be a system in place to monitor problems and verify accuracy.



The laboratory must self assess ungraded results and PT results where the score does not accurately reflect their results. (PT programs routinely report 100 percent performance for ungraded challenges.) The laboratory should be looking at the PT for shifts/trends in PT results and correlating to QC results. Any remedial or corrective actions must be monitored for effectiveness. Ungraded PT challenges should be compared to the most common responses given.

Can your laboratory staff recognize potential problems? Was the problem pre-analytic, analytic or post-analytic? Is additional training required of the staff? Are corrective actions taken which are appropriate? Is effectiveness of remedial action evaluated? Are all actions documented? Have patients been affected by this failure? When did the problem start?

The laboratory should discontinue the testing of non-regulated analytes when the laboratory cannot verify the accuracy and reliability of its test results, when they cannot guarantee that patient results are not affected or cannot determine the cause of the problem.

If your laboratory would like to receive *CLIA Bits* electronically, please send your e-mail address to bweidner@state.nd.us.

Inside this issue:

Special points of interest:

- Steps to take when you receive an unacceptable proficiency testing result on non-regulated analytes.
- OraQuick Rapid HIV-1 Antibody test
- Notify the state agency of changes.

Quality Assurance Guidelines for Rapid HIV Test

"Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test" is a document which provides quality assurance guidance for laboratories using or planning to use the OraQuick Rapid HIV-1 Antibody Test. The OraQuick Rapid HIV-1 Antibody Test is the first HIV test that has been granted waived status under CLIA.

The quality assurance guidance was developed by the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the U.S. Department of Defense (DOD), along with other industry experts. These guidelines are currently available at:

www.phppo.cdc.gov/dls/pdf/HIV/QA_Guidlines_OraQuick.pdf

More CLIA information is available at:

www.health.state.nd.us/hf/North_Dakota_clinical_laboratories.htm

This site now includes a new listing of CLIA labs and a searchable database.

Notification of Changes

Laboratories in North Dakota are going through constant change. CLIA regulation 493.51 requires laboratories to notify the state agency, in writing, **within 30 days** of any change in:

- Ownership
- Name
- Location
- Director
- Technical supervisor

Laboratories are also required to notify the state agency or accreditation organization in writing, **within 6 months**, of any additions, deletions or changes in test methodologies, specialties and subspecialties (i.e. new/different instruments, kits, tests, etc). Medicare reimbursement is directly tied to the testing you are authorized by CLIA to perform. Therefore, it is possible that reimbursement may be denied if you are not authorized to test in a specialty.

Once notification is received, your certificate will be reviewed to see if these changes require a revision of your CLIA fees and/or certificate. Generally, when a laboratory is assigned a CLIA number, the laboratory retains this number even if it withdraws from CLIA, changes certificate type, ownership, location, name or director. A CLIA number will not be reassigned to another laboratory for any reason. Failure to furnish notification of changes may result in sanctions from a monetary penalty up to revocation of your CLIA certificate.

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